

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

[illegible]

**THE CITY OF NEW YORK AND NEW YORK COUNTIES' SUR-RESPONSE AND
OBJECTION TO THE MOTION TO APPROVE THE PROPOSED SETTLEMENT
BETWEEN CALIFORNIA, FLORIDA AND RELATOR VEN-A-CARE OF THE FLORIDA
KEYS ON BEHALF OF ITSELF AND THE UNITED STATES AND SCHERING-PLOUGH,
SCHERING & WARRICK**

The Reply Memoranda filed by the proponents of this settlement do nothing to allay the The City of New York and New York Counties’ (collectively “NY Counties”) concerns with it, as set forth in the NY Counties’ Response and Objection to the Motion to Approve the Proposed Settlement, filed August 28, 2009 [Docket No. 6435] (“NY Counties Objection”).

I.

The Reply Memoranda entirely ignore the NY Counties' observation that Schering's own expert, Sumanth Addanki, found that 20 of the 30 Schering Covered Drugs have annual

AMP/AWP spreads in excess of 30% for certain years. NY Counties Objection at Point 2. The advocates for the settlement make no effort to reconcile Dr. Addanki's findings with the proposition that claims for the Schering Covered Drugs have no value whatsoever and should be released for \$0.

On Reply, Schering introduces the affidavit of Paul F. Charnetzki, C.P.A. to "demonstrate [that]...a settlement payment of between \$26.2 million and \$32.1 million is fair, reasonable and adequate compensation to the United States for a complete release of the Federal Share." Defendant Schering's Reply Memorandum, filed September 4, 2009 [Docket No. 6485] ("Schering Reply") at 18. But, Schering does not explain why it specifically instructed Mr. Charnetzki to ignore entirely the Schering brand drugs and consider only Warrick drugs. *See* Affidavit of Paul F. Charnetzki, dated September 4, 2009 ("Charnetzki Aff.") [Dkt. No. 6486] at 2.1.

The instant record simply does not support the proposition that claims for the Schering Covered Drugs should be released for no consideration whatsoever. Likewise, the instant record does not support entry of findings that "None of the WACs or AWP's for the Schering-brand drugs analyzed in Exhibit A to the Settlement Agreement constituted false or fraudulent statements, or were misleading, deceptive or unfair....". Proposed Order Approving Settlement and Dismissal with Prejudice of Schering-Plough Corporation, Schering Corporation and Warrick Pharmaceuticals Corporation (June 26, 2009)(Dkt. # 6173, Sub. #231, Exh C. at 5-7).

II.

The Reply Memoranda ignore that there is nothing in the record demonstrating that Schering's AMPs are the same as ASPs and therefore may serve as appropriate proxies for ASP in an ASP/AWP spread test. New York Counties' Objection at 4-5. Indeed, in his affidavit

purportedly assessing the value of the federal exposure, Mr. Charnetzki appears to take the position that Schering's AMPs must be marked up by 250% or 300% to arrive at ASP. Charnetzki Aff at 2.5. If the NY Counties understand Mr. Charnetzki's methodology correctly, it would contradict the *ipse dixit* Schering has previously offered to this Court about the relationship between Schering's ASPs and AMPs, including in the Proposed Findings. There, Schering *asks this Court to find* that ASP "can be measured, *conservatively* by Average Manufacturers' Price or AMP calculated in accordance with all applicable HCFA/CMS regulations." Proposed Order Approving Settlement and Dismissal with Prejudice of Schering-Plough Corporation, Schering Corporation and Warrick Pharmaceuticals Corporation (June 26, 2009)(Dkt. # 6173, Sub. #231, Exh C. at 5-7) ("Proposed Findings"). If Schering's view is, as it has previously said and as it has asked this Court to "find", that AMP = ASP then Mr. Charnetzki would have had no basis to multiply AMP by 250% or 300% to arrive at an ASP in the context of valuing federal exposure. Accordingly, Mr. Charnetzki's conclusion that federal exposure was something between \$26-\$32 million would be grossly understated.

Given the NY Counties' understanding that the Court does not intend the September 25, 2009 hearing to be evidentiary in nature¹, and the fact that Mr. Charnetzki was introduced to all for the first time on September 4, 2009, the NY Counties have not yet deposed Mr. Charnetzki on his methodologies or rationales. The NY Counties will seek such a deposition should this Court schedule an evidentiary hearing on the fairness of the proposed settlement. For now, however, the point remains that the instant record does not support the proposition that Schering's AMPs are the same as ASPs.

III.

The NY Counties noted in their Objection that this Court has yet to rule on the proper methodology for conducting the WAC List Price test and that, therefore, it cannot be stated on the instant record which Schering Covered Drugs pass that test. *See* New York Counties' Objection at 3-4. The Reply Memoranda are entirely silent on the point. The NY Counties stand by their Objection. Until the Court rules on how the WAC List Price test is to be conducted, it would be premature to conclude which Schering Covered Drugs pass that test.

IV.

The Reply Memoranda also ignore the NY Counties' observation that there is no record evidence that the 30% yardstick should apply to New York Medicaid and this Court's acknowledgement on July 24, 2009 that the issue was open in the New York Counties case. *See* New York Counties' Objection at 6. The instant record cannot support entry of a generalized finding that "government payors, such as Medicaid, did not reasonably consider published AWP's that were generally within 30% of the average selling price for that drug (measured, conservatively by Average Manufacturers' Price or AMP calculated in accordance with all applicable HCFA/CMS regulations)". Proposed Findings at 5-7.

IV.

While, as noted above, it is the NY Counties' expectation that the September 25, 2009 hearing will not be evidentiary in nature and while they have yet to depose the newly-introduced Mr. Charnetzki, the NY Counties offer the following additional preliminary observations regarding his affidavit which may call into question its reliability.

¹ *See*, Transcript of July 24, 2009 Scheduling Conference at 15-24.

(1) As stated above, Mr. Charnetzki fails to include any analysis of exposure for the Schering Covered Drugs even though Schering's expert Dr. Addanki has found that 20 of 30 have annual AMP/AWP spreads in excess of 30% for certain years;

(2) Mr. Charnetzki's conclusion that the federal exposure is valued \$26-32 million appears to rest on the assumption that Schering's AMPs must be multiplied by 250% or 300% to arrive at an ASP. If that is the case, Dr. Charnetzki's methodology appears to be odds with Schering's request that this Court find that its ASPs may conservatively be measured by AMP. *See Proposed Findings at 5-7.* Moreover, in such case, Mr. Charnetzki's assessment of the value of federal exposure would be grossly understated.

(3) Mr. Charnetzki was apparently instructed by Schering to assume that Schering would face no exposure whatsoever for drugs once they were subject to a FUL and even if the FUL was later removed. *See Charnetzki Aff. at 2.3.* If this is an accurate read of what Mr. Charnetzki was asked to do, the instruction would result in an improper and/or premature understatement of Schering's exposure. The issue of any defendant manufacturer's liability for inflated FULs is hotly contested and unresolved in the context of the NY Counties case, as this Court and Schering are well aware. Moreover, whatever the outcome on that issue in the NY Counties' case, given that FULs are included in the "lesser of" reimbursement formulas of most states, the existence of a FUL is irrelevant entirely to the question of whether Schering's false AWP and WACs caused states to over-reimburse. And finally, there can be no justification whatsoever for assuming no exposure for those drugs that were on a FUL for some period of time and thereafter came off the FUL. Even under New York's reimbursement formula, once off FUL those Warrick drugs would have been reimbursed on the basis of AWP. N.Y. Soc. Serv. L. 367a-9. Given that the overwhelming majority of Warrick drugs were, for least at some point during the

relevant period, subject to a FUL, Mr. Charnetzky's removal of expenditures associated with FUL reimbursements would also grossly understate Schering/Warrick's federal exposure.

V.

Two parting comments on discovery. First, Schering's Reply concedes *sub silentio* that 27 CMS and 4 OIG witnesses have been deposed by defendants in MDL 1456. Schering Reply at 25-26. Presumably this will put to rest, at least in the context of any MDL cases, the notion that Schering has not had ample opportunity to develop its defenses insofar as they involve federal witnesses.

Second, for all the references to the "voluminous record in the MDL" (*e.g.*, Schering Reply at 26) and the "extensive record on Schering Brand Drugs" (*e.g.* Joint Memorandum in Support of Motion for Approval of the Settlement between California, Florida, and Relator Ven-A-Care of the Florida Keys on Behalf of Itself and the United States and Schering-Plough, Schering, and Warrick [Dkt. No. 6360] at 5), the fact is that just this week Schering reconfirmed to the NY Counties that it has never produced data in the MDL related to any post-2003 conduct nor all responsive rebate data. And just yesterday, the NY Counties received Schering's response to the interrogatories and document requests served on August 11, 2009 by the NY Counties in their effort to understand what Schering meant when, in the context of the proposed settlement, it referred to the "extensive discovery with respect to Schering's brand drugs". Schering's responses are attached as A hereto. They speak for themselves and suggest, regrettably, that Schering has no genuine interest in assisting the NY Counties or the Court in truly understanding the record as it concerns Schering brand drugs.

CONCLUSION

For all the foregoing reasons, the NY Counties respectfully request that the Court reject the Settlement as drafted.

Dated: September 11, 2009

Respectfully submitted,

**City of New York and New York Counties in
MDL 1456 except Nassau and Orange by**

KIRBY McINERNEY, LLP
825 Third Avenue
New York, New York 10022
(212) 371-6600

By: /s/ Joanne M. Cicala
Joanne M. Cicala
James P. Carroll, Jr.
Jocelyn R. Normand
Kathryn B. Allen

Ross B. Brooks, Esq.
MILBERG LLP
One Pennsylvania Plaza
New York, NY 10119
(212) 594-5300
Special Counsel for the County of Nassau

Theresa A. Vitello, Esq.
LEVY PHILLIPS &
KONIGSBERG, LLP
800 Third Avenue
New York, NY 10022
(212) 605-6205
Counsel for the County of Orange

CERTIFICATE OF SERVICE

I, Kathryn B. Allen, hereby certify that I caused a true and correct copy of the foregoing to be served on counsel of record via electronic service pursuant to paragraph 11 of Case Management Order No. 2, by sending a copy to LexisNexis File and Serve for posting and notification to all parties.

Dated: September 11, 2009

/s/ Kathryn B. Allen
Kathryn B. Allen
Kirby McInerney LLP
825 Third Avenue, 16th Floor
New York, NY 10022
(212) 371-6600